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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

WYETH, Plaintiff, v. ORGENUS PHARMA INC. AND ORCHID CHEMICALS & PHARMACEUTICALS LTD., Defendants.	Civil Action No. 3:09-cv-03235 (FLW)(DEA) *ELECTRONICALLY FILED* **ANSWER OF ORGENUS PHARMA INC. AND ORCHID CHEMICALS & PHARMACEUTICALS LTD.** **COUNTERCLAIMS OF ORCHID CHEMICALS & PHARMACEUTICALS LTD.**

STATEMENT PURSUANT TO L. CIV. R. 10.1

Defendant Orchid Chemicals & Pharmaceuticals Ltd. is a company organized and existing under the laws of India with its principal place of business at Orchid Towers, #313, Valluvar Kottam High Road, Nungambakkam, Chennai – 600 034, Tamil Nadu, India. Defendant Orgenus Pharma Inc. is a corporation incorporated under the laws of the State of New Jersey with its principal place of business at 700 Alexander Park, Suite 104, Princeton, NJ 08540.

ANSWER

Defendants Orchid Chemicals & Pharmaceuticals Ltd. and Orgenus Pharma Inc. (collectively, "Orchid") hereby answer the Complaint of Plaintiff Wyeth ("Wyeth") and counterclaim as follows. Orchid hereby denies all allegations not otherwise admitted or denied.

Response to the Parties

1. Orchid lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 1. Orchid therefore denies the allegations in paragraph 1.

2. In response to paragraph 2, Orchid admits that Orchid Chemicals & Pharmaceuticals Ltd. is a company organized and existing under the laws of India with its principal place of business at Orchid Towers, #313, Valluvar Kottam High Road, Nungambakkam, Chennai – 600 034, Tamil Nadu, India.

3. In response to paragraph 3, Orchid admits that Orgenus Pharma Inc. is a corporation incorporated under the laws of the State of New Jersey with its principal place of business at 700 Alexander Park, Suite 104, Princeton, New Jersey 08540.

4. In response to paragraph 4, Orchid admits that Orgenus Pharma Inc. is a subsidiary of Orchid Pharmaceuticals Inc., which is itself a wholly-owned subsidiary of Orchid Chemicals & Pharmaceuticals Ltd. Orchid also admits that Orgenus Pharma Inc. is Orchid Chemicals & Pharmaceuticals Ltd.'s primary business contact in the United States.

5. Orchid denies the allegations in paragraph 5.

6. Orchid denies the allegations in paragraph 6.

Response to Nature of the Action

7. In response to paragraph 7, Orchid admits that Wyeth alleges that this is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and in particular under 35 U.S.C. § 271(e). Orchid admits that Wyeth alleges that this action relates to Abbreviated New Drug Application ("ANDA") No. 91-123 filed by Orchid with the United States Food and Drug Administration ("FDA") for approval to market Venlafaxine

Hydrocholoride Extended-Release Capsules, 37.5 mg, 75 mg and 150 mg (the "Orchid ANDA" or "ANDA No. 91-123"). Orchid denies any and all liability.

Response to Jurisdiction and Venue

8. In response to paragraph 8, Orchid admits that this Court has jurisdiction over the subject matter of the claims against Orchid pursuant to 28 U.S.C. §§ 1331 and 1338(a). .

9. In response to paragraph 9, Orchid admits that Orgenus Pharma Inc. has its principal place of business at 700 Alexander Park, Suite 104, Princeton, New Jersey, conducts business in New Jersey, and is incorporated in New Jersey.

10. Orchid denies the allegations of paragraph 10, except admits that Orgenus Pharma Inc. forwarded a CD of ANDA No. 91-123 to FDA by courier, that ANDA No. 91-123 lists Ms. Diana Wilk / Mr. Satish Srinivasan of Orgenus Pharma Inc. as "US Agent," and that Ms. Diana Wilk signed Form FDA 356h and Form FDA 3674 as "US Agent."

11. In response to paragraph 11, Orchid admits that this Court has personal jurisdiction over Orgenus Pharma Inc.

12. Orchid denies the allegation of paragraph 12, except admits that Orchid Chemicals & Pharmaceuticals Ltd. is registered to do business in New Jersey, has appointed Corporation Service Company of West Trenton, New Jersey to accept service of process on its behalf, and has designated Mr. Satish Srinivasan, Orgenus Pharma Inc., to accept service of process in connection with a lawsuit filed with respect to ANDA No. 91-123.

13. Orchid denies the allegations of paragraph 13, except admits that Orchid Chemicals & Pharmaceuticals Ltd. is in the business of developing, manufacturing, marketing, and selling generic drugs.

14. In response to paragraph 14, Orchid admits that Orchid Chemicals & Pharmaceuticals Ltd.'s website notes under the heading "Subsidiaries" that Orgenus Pharma Inc. is its primary business contact for the United States and Canada and that this website provides contact information for Orgenus Pharma Inc. and its Executive Vice President for Business Development and Operations, Mr. Satish Srinivasan.

15. Orchid denies the allegations of paragraph 15, except admits that the 2007-08 annual report for Orchid Chemicals & Pharmaceuticals Ltd., available on its website, lists Orgenus Pharma Inc. as a subsidiary of Orchid Pharmaceuticals Inc., which is itself a wholly owned subsidiary of Orchid Chemicals & Pharmaceuticals Ltd. and notes that the nature of Orgenus Pharma Inc.'s business in the United States is "services."

16. Orchid denies the allegations in paragraph 16.

17. Orchid denies the allegations in paragraph 17.

18. Orchid denies the allegations in paragraph 18.

19. Orchid denies the allegations in paragraph 19.

20. Orchid denies the allegations in paragraph 20.

21. Orchid denies the allegations in paragraph 21.

22. Orchid denies the allegations in paragraph 22.

23. Orchid denies the allegations in paragraph 23.

24. Orchid denies the allegations of paragraph 24, except admits that Orgenus Pharma Inc. forwarded a CD of ANDA No. 91-123 to FDA by courier, that ANDA No. 91-123 lists Ms. Diana Wilk / Mr. Satish Srinivasan of Orgenus Pharma Inc. as "US Agent," and that Ms. Diana Wilk signed Form FDA 356h and Form FDA 3674 as "US Agent."

25. Orchid denies the allegations in paragraph 25. However, for the purpose of this particular action, Orchid does not contest that Orchid Chemicals & Pharmaceuticals Ltd. is subject to personal jurisdiction in New Jersey.

26. In response to paragraph 26, Orchid admits that venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

Response to Background

27. Orchid lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 27. Orchid therefore denies the allegations in paragraph 27.

28. Orchid denies the allegations of paragraph 28, except admits that Orchid filed with FDA ANDA No. 91-123 under 21 U.S.C. § 355(j) requesting approval for the commercial manufacture, use, and sale of Venlafaxine HCl Extended-Release Capsules in 37.5 mg, 75 mg, and 150 mg dosage strengths.

29. In response to paragraph 29, Orchid admits that Orchid Chemicals & Pharmaceuticals Ltd. notified Wyeth by letter dated May 19, 2009 that it had filed ANDA No. 91-123 seeking approval to market Venlafaxine HCl Extended-Release Capsules in 37.5 mg, 75 mg, and 150 mg dosage strengths and that it was providing information to Wyeth pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). On information and belief, Wyeth received that letter on or about May 21, 2009.

Response to First Count for Infringement by Orchid Chemicals & Pharmaceuticals Ltd. and Orgenus Pharma Inc. of United States Patent No. 6,274,171 B1

30. Orchid repeats and incorporates by reference its responses in paragraphs 1-29.

31. In response to paragraph 31, Orchid admits that the United States Patent and Trademark Office issued United States Patent No. 6,274,171 B1 ("the '171 patent"), entitled "Extended Release Formulation of Venlafaxine Hydrochloride," on August 14, 2001. Orchid also admits that FDA has listed the '171 patent in the publication "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as "The Orange Book" ("The Orange Book"), in connection with EFFEXOR® XR. Orchid further admits that a copy of the '171 patent is attached as Exhibit A to Wyeth's complaint. Orchid lacks knowledge or information sufficient to form a belief as to whether Wyeth is the owner by assignment of the '171 patent, and therefore denies this allegation. Orchid denies the remaining allegations in paragraph 31 and specifically denies that the '171 patent was duly and legally issued.

32. Orchid denies the allegations of paragraph 32, except admits that Orchid filed ANDA No. 91-123 seeking approval to market the Orchid Venlafaxine HCl Extended-Release Capsules in the United States prior to the expiration of the '171 patent. Orchid also admits that Orchid filed with FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. §

314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '171 patent are invalid, unenforceable, and/or not infringed.

33. Orchid denies the allegations in paragraph 33.

34. Orchid denies the allegations in paragraph 34.

35. Orchid denies the allegations in paragraph 35.

36. Orchid denies the allegations in paragraph 36.

37. Orchid denies the allegations in paragraph 37.

38. Orchid denies the allegations in paragraph 38.

39. Orchid denies the allegations in paragraph 39.

40. Orchid denies the allegations in paragraph 40.

Response to Second Count for Infringement by Orchid Chemicals & Pharmaceuticals Ltd. and Orchid Pharma Inc. of United States Patent No. 6,403,120 B1

41. Orchid repeats and incorporates by reference its responses in paragraphs 1-40.

42. In response to paragraph 42, Orchid admits that the United States Patent and Trademark Office issued United States Patent No. 6,403,120 B1 ("the '120 patent"), entitled "Extended Release Formulation of Venlafaxine Hydrochloride," on June 11, 2002. Orchid also admits that FDA has listed the '120 patent in The Orange Book in connection with EFFEXOR® XR. Orchid further admits that a copy of the '120 patent is attached as Exhibit B to Wyeth's complaint. Orchid lacks knowledge or information sufficient to form a belief as to whether Wyeth is the owner by assignment of the '120 patent, and therefore denies this allegation. Orchid denies the remaining allegations in paragraph 42 and specifically denies that the '120 patent was duly and legally issued.

43. Orchid denies the allegations of paragraph 43, except admits that Orchid filed ANDA No. 91-123 seeking approval to market the Orchid Venlafaxine HCl Extended-Release Capsules in the United States prior to the expiration of the '120 patent. Orchid also admits that Orchid filed with FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. §

314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '120 patent are invalid, unenforceable, and/or not infringed.

44. Orchid denies the allegations in paragraph 44.

45. Orchid denies the allegations in paragraph 45.

46. Orchid denies the allegations in paragraph 46.

47. Orchid denies the allegations in paragraph 47.

48. Orchid denies the allegations in paragraph 48.

49. Orchid denies the allegations in paragraph 49.

50. Orchid denies the allegations in paragraph 50.

51. Orchid denies the allegations in paragraph 51.

Response to Third Count for Infringement by Orchid Chemicals & Pharmaceuticals Ltd. and Orchid Pharma Inc. of United States Patent No. 6,419,958 B2

52. Orchid repeats and incorporates by reference its responses in paragraphs 1-51.

53. In response to paragraph 53, Orchid admits that the United States Patent and Trademark Office issued United States Patent No. 6,419,958 B2 ("the '958 patent"), entitled "Extended Release Formulation of Venlafaxine Hydrochloride," on July 16, 2002. Orchid also admits that FDA has listed the '958 patent in The Orange Book in connection with EFFEXOR® XR. Orchid further admits that a copy of the '958 patent is attached as Exhibit C to Wyeth's complaint. Orchid lacks knowledge or information sufficient to form a belief as to whether Wyeth is the owner by assignment of the '958 patent, and therefore denies this allegation. Orchid denies the remaining allegations in paragraph 53 and specifically denies that the '958 patent was duly and legally issued.

54. Orchid denies the allegations of paragraph 54, except admits that Orchid filed ANDA No. 91-123 seeking approval to market the Orchid Venlafaxine HCl Extended-Release Capsules in the United States prior to the expiration of the '958 patent. Orchid also admits that Orchid filed with FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. §

314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '958 patent are invalid, unenforceable, and/or not infringed.

55. Orchid denies the allegations in paragraph 55.

56. Orchid denies the allegations in paragraph 56.

57. Orchid denies the allegations in paragraph 57.

58. Orchid denies the allegations in paragraph 58.

59. Orchid denies the allegations in paragraph 59.

60. Orchid denies the allegations in paragraph 60.

61. Orchid denies the allegations in paragraph 61.

62. Orchid denies the allegations in paragraph 62.

Response to Fourth Count for Infringement by Orgenus Pharma Inc. of United States Patent Nos. 6,274,171 B1, 6,403,120 B1 and 6,419,958 B2

63. Orchid repeats and incorporates by reference its responses in paragraphs 1-62.

64. Orchid denies the allegations of paragraph 64, except admits that Orgenus Pharma Inc. forwarded a CD of ANDA No. 91-123 to FDA by courier, that ANDA No. 91-123 lists Ms. Diana Wilk / Mr. Satish Srinivasan of Orgenus Pharma Inc. as "US Agent," and that Ms. Diana Wilk signed Form FDA 356h and Form FDA 3674 as "US Agent."

65. Orchid denies the allegations in paragraph 65.

66. Orchid denies the allegations in paragraph 66.

Response to Fifth Count For Infringement by Orchid Chemicals & Pharmaceuticals of United States Patent Nos. 6,274,171 B1, 6,403,120 B1 and 6,419,958 B2

67. Orchid repeats and incorporates by reference its responses in paragraphs 1-66.

68. Orchid denies the allegations of paragraph 68, except admits that Orchid Chemicals & Pharmaceuticals Ltd. filed ANDA No. 91-123 with FDA and that it was aware of the '171, '120, and '958 patents at the time.

69. Orchid denies the allegations in paragraph 69.

70. Orchid denies the allegations in paragraph 70.

Response to Prayer for Relief

Orchid denies that Wyeth is entitled to any of the relief that it seeks in the prayer.

AFFIRMATIVE DEFENSES

Orchid alleges and asserts the following affirmative defenses in response to the allegations in Wyeth's Complaint:

First Affirmative Defense

Invalidity of the '171 Patent

71. Each claim of the '171 patent is invalid for failure to meet one or more of the requirements of Title 35, United States Code, including, *inter alia*, §§ 101, 102, 103, 112, and/or for double patenting.

Second Affirmative Defense

Invalidity of the '120 Patent

72. Each claim of the '120 patent is invalid for failure to meet one or more of the requirements of Title 35, United States Code, including, *inter alia*, §§ 101, 102, 103, 112, and/or for double patenting.

Third Affirmative Defense

Invalidity of the '958 Patent

73. Each claim of the '958 patent is invalid for failure to meet one or more of the requirements of Title 35, United States Code, including, *inter alia*, §§ 101, 102, 103, 112, and/or for double patenting.

Fourth Affirmative Defense

Non-Infringement of the '171 Patent

74. The commercial manufacture, use, offer for sale, sale or importation of the product described in ANDA No. 91-123 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any claim of the '171 patent. For this reason, the submission of ANDA No. 91-123 to the FDA was not an act of infringement under 35 U.S.C. § 271(e).

Fifth Affirmative Defense

Non-Infringement of the '120 Patent

75. The commercial manufacture, use, offer for sale, sale or importation of the product described in ANDA No. 91-123 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any claim of the '120 patent. For this reason, the submission of ANDA No. 91-123 to the FDA was not an act of infringement under 35 U.S.C. § 271(e).

Sixth Affirmative Defense

Non-Infringement of the '958 Patent

76. The commercial manufacture, use, offer for sale, sale or importation of the product described in ANDA No. 91-123 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any claim of the '958 patent. For this reason, the submission of ANDA No. 91-123 to the FDA was not an act of infringement under 35 U.S.C. § 271(e).

Seventh Affirmative Defense

Unenforceability of the '171 Patent

77. The '171 patent is unenforceable due to inequitable conduct before the United States Patent and Trademark Office for the reasons set forth in paragraphs 1-98 of the counterclaims below, and incorporated herein by reference.

Eighth Affirmative Defense

Unenforceability of the '120 Patent

78. The '120 patent is unenforceable due to inequitable conduct before the United States Patent and Trademark Office for the reasons set forth in paragraphs 1-98 of the counterclaims below, and incorporated herein by reference.

Ninth Affirmative Defense

Unenforceability of the '958 Patent

79. The '958 patent is unenforceable due to inequitable conduct before the United States Patent and Trademark Office for the reasons set forth in paragraphs 1-98 of the counterclaims below, and incorporated herein by reference.

COUNTERCLAIMS

Defendant/Counterclaimant Orchid Chemicals & Pharmaceuticals Ltd. ("Counterclaimant") brings the following Counterclaims against Plaintiff/Counterdefendant Wyeth ("Counterdefendant").

The Parties

1. Counterclaimant Orchid Chemicals & Pharmaceuticals Ltd. is a company organized and existing under the laws of India with its principal place of business at Orchid Towers, #313, Valluvar Kottam High Road, Nungambakkam, Chennai – 600 034, Tamil Nadu, India.

2. On information and belief, Counterdefendant Wyeth is a corporation incorporated under the laws of the State of Delaware with its principal place of business at Five Giralda Farms, Madison, New Jersey 07940.

Nature of the Action

3. This is an action for a declaration of patent noninfringement, invalidity and unenforceability arising under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, and the patent laws of the United States, 35 U.S.C. § 1 *et seq.*

Jurisdiction and Venue

4. This Court has jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

5. This Court has personal jurisdiction over Wyeth because, *inter alia*, Wyeth has submitted to the jurisdiction of this Court and, on information and belief, Wyeth has its principal place of business at Five Giralda Farms, Madison, New Jersey 07940.

6. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b)-(c) and 1400, as well as Counterdefendant's choice of forum.

7. Wyeth has created an actual controversy between itself and Orchid through its listing of the '171, '120, and '958 patents in the Orange Book, as well as by virtue of its allegations that Orchid's submission of ANDA No. 91-123 to the FDA constituted an act of infringement under 35 U.S.C. § 271(e) with regard to one or more claims of the '171, '120, and '958 patents.

The Patents and Related Drug Product

8. Pursuant to 21 U.S.C. § 355(j), the Federal Food, Drug and Cosmetic Act ("FDCA") authorizes a generic drug company to file an ANDA with FDA for approval of a generic drug product that has the same active ingredient as, and is bioequivalent to, a drug product that FDA has already approved pursuant to an NDA.

9. Pursuant to 21 U.S.C. § 355(b), the FDCA requires NDA holders to submit to FDA the patent numbers and expiration dates of any patent that claims the drug or a method of using the drug for which an NDA is filed. FDA then lists those patents in The Orange Book.

10. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), if a generic drug company seeks approval to market a generic drug product prior to the expiration of a patent listed in the Orange Book, the generic drug company is required by law to include a certification in its ANDA that the patent is invalid, unenforceable, or will not be infringed by the generic drug product ("Paragraph IV Certification").

11. Pursuant to 21 U.S.C. § 355(j)(2)(B), if the generic drug company includes a Paragraph IV Certification in its ANDA, the generic drug company must send the NDA holder and the patent owner notice of that certification, including a detailed statement of the factual and legal basis for the generic drug company's opinion that the patent is invalid, unenforceable or will not be infringed ("Notice Letter").

12. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), if a suit for patent infringement is brought within 45 days of receiving the Notice Letter, FDA generally may not grant final

approval for the generic drug company's ANDA for 30 months or until resolution of the patent infringement action.

13. On information and belief, Wyeth is the holder of NDA No. 20-699 for an extended release dosage form containing venlafaxine hydrochloride. On information and belief, the trade name of Wyeth's venlafaxine hydrochloride is EFFEXOR® XR.

14. On information and belief, Wyeth is the owner of United States Patent No. 6,274,171 ("the '171 patent"), United States Patent No. 6,403,120 ("the 120 patent"), and United States Patent No. 6,419,958 ("the '958 patent"). Copies of the '171, '120, and '958 patents are attached respectively as Exhibits A, B and C to Wyeth's Complaint.

15. On information and belief, Wyeth requested that FDA list the '171, '120, and '958 patents in The Orange Book for EFFEXOR® XR, NDA No. 20-699.

16. Orchid Chemicals & Pharmaceuticals Ltd. filed ANDA No. 91-123 with FDA seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of the venlafaxine extended release product described in its ANDA prior to the expiration of the '171, '958, and '120 patents. Orchid Chemicals & Pharmaceuticals Ltd. included in ANDA No. 91-123 a Paragraph IV Certification stating that, in the opinion of Orchid Chemicals & Pharmaceuticals Ltd., and to the best of its knowledge, the '171, '958, and '120 patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, importation, offer for sale, or sale of the venlafaxine extended release product described in its ANDA.

17. By letter dated May 19, 2009, Orchid Chemicals & Pharmaceuticals Ltd. sent Wyeth a Notice Letter that included a detailed statement of the factual and legal basis for Orchid Chemicals & Pharmaceuticals Ltd.'s opinion that its venlafaxine ANDA product would not infringe any valid and enforceable claim of the '171, '958, and '120 patents. Pursuant to 21 U.S.C. § 355(j)(5)(C), the Notice Letter was accompanied by an Offer of Confidential Access to ANDA No. 91-123. On or about May 21, 2009, Wyeth received the Notice Letter.

18. On or about July 2, 2009, Wyeth filed a Complaint in this action against Orchid Chemicals & Pharmaceuticals Ltd. and Orgenus Pharma Inc. alleging infringement of the '171, '958, and '120 patents. Wyeth asserted in its Complaint that the filing of ANDA No. 91-123 was an act of infringement of the '171, '958, and '120 patents under 35 U.S.C. § 271(e)(2). Wyeth also asserted in its Complaint that the commercial manufacture, use, offer for sale, sale, or importation of the product described in ANDA No. 91-123 would infringe one or more claims of the '171, '958, and '120 patents under 35 U.S.C. § 271.

19. Wyeth's assertion against Orchid of claims of infringement of the '171, '120, and '958 patents after being advised by Orchid Chemicals & Pharmaceuticals Ltd. in its Notice Letter that there is no basis for those claims renders the Counterclaimant's case exceptional within the meaning of 35 U.S.C. § 285.

20. Orchid Chemicals & Pharmaceuticals Ltd. has no adequate remedy at law. The actions and assertions made by Wyeth with respect to the '171, '958, and '120 patents have caused and will continue to cause irreparable injury to the rights of Orchid Chemicals & Pharmaceuticals Ltd.

Prosecution of Wyeth's Patents

Wyeth's Upton Patent

21. On January 30, 1995, American Home Products Corporation (now Wyeth via a name change; hereinafter simply referred to as Wyeth) filed patent application No. 08/380,903, that disclosed the administration of venlafaxine as a sustained oral administration form or time-release form. ("the Upton application").

22. The Upton application issued as U.S. Patent No. 5,506,270 ("the Upton patent") on April 9, 1996.

The '137 Parent Application

23. On March 20, 1997, Wyeth filed patent application No. 08/821,137 (the "'137 parent application").

24. Deborah M. Sherman was named as the sole inventor on the '137 parent application.

25. At least the following Wyeth attorneys were involved in the prosecution of the '137 parent application: Ronald W. Alice and Robert F. Boswell.

26. Claims 1, 9, and 10 of the '137 parent application respectively read as follows:

> 1. An encapsulated, extended release formulation of venlafaxine hydrochloride comprising a hard gelatin capsule containing a therapeutically effective amount of spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and hydroxypropyl methycellulose coated with ethyl cellulose and hydroxypropylmethylcellulose.
>
> 9. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.
>
> 10. A method for eliminating the troughs and peaks of drug concentration in a patients blood plasma attending the therapeutic metabolism of plural daily doses of which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

27. On July 30, 1997, the examiner of the '137 parent application, Examiner Amy Hulina, cited Upton U.S. Patent No. 5,506,270; Wong U.S. Patent No. 5,532,244; Husbands U.S. Patent No. 5,530,013; Husbands U.S. Patent No. 4,535,186; and Husbands U.S. Patent No. 4,761,501 on Form PTO-892.

28. The five patents cited by Examiner Hulina on the July 30, 1997 Form PTO-892 were material to the patentability of the pending claims in the '137 parent application.

29. On July 30, 1997, Robert F. Boswell of Wyeth conducted a telephonic interview with Examiner Hulina.

30. During the interview, Robert F. Boswell of Wyeth:

> Agreed to amend claims 9 and 10 to depend from claim 1 to avoid rejection over Upton which discloses extended release venlafaxine at col. 5, lines 25-27.

31. In response to the applicant's agreement, Examiner Hulina issued a Notice of Allowability, which included an Examiner's Amendment that made claims 9 and 10 of the '137 parent application dependent upon claim 1.

32. Robert F. Boswell of Wyeth authorized the examiner's amendment in the telephone interview with the examiner on July 30, 1997.

33. Examiner Hulina provided the following statement of reason for allowance:

> The prior art does not teach or suggest the specific extended release claim formulation according to claim 1.

34. Wyeth permitted the '137 parent application to go abandoned by not paying the issue fee that was due on November 5, 1997.

The '328 Application

35. On November 5, 1997, Wyeth filed continuation-in-part application No. 08/964,328 ("the '328 application").

36. Deborah M. Sherman, John C. Clark and John U. Lamer were named joint inventors on the '328 application.

37. At least the following Wyeth attorneys were involved in the prosecution of the '328 application: Ronald W. Alice, Robert F. Boswell, Steven R. Eck, and Arthur G. Seifert.

38. The '328 application was assigned to Examiner James Spear.

39. The '328 application included the following independent method claims:

> 13. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

> 14. A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

40. Claim 13 of the '328 application was identical to claim 9 of the '137 parent application, prior to its amendment "to avoid rejection over Upton."

41. Claim 14 of the '328 application was substantially similar to claim 10 of the '137 parent application, prior to its amendment "to avoid rejection over Upton."

42. At least Deborah M. Sherman, John C. Clark, John U. Lamer, Ronald W. Alice, Robert F. Boswell, Steven R. Eck, and Arthur G. Seifert failed to disclose to the new examiner (Examiner James Spear) the earlier examiner's (Examiner Amy Hulina's) requirement for an amendment of the identical and substantially similar claims "to avoid rejection over Upton" and the fact that Wyeth had acquiesced to Examiner Hulia's requirement and agreed to narrow the scope of the identical and substantially similar claims in order "to avoid rejection over Upton."

43. The information withheld by the named inventors and/or prosecuting attorneys was material to the patentability of the pending claims.

44. On information and belief, the named inventors and/or prosecuting attorneys withheld such material information from the examiner in order to prosecute claims substantially similar to the previously rejected claims and did so with an intent to mislead or deceive the USPTO.

45. Wyeth permitted the '328 application to go abandoned by failing to respond to an Office Action by January 21, 2000.

The '171 Patent

46. On January 20, 2000, Wyeth filed Application No. 09/488,629 ("the '629 application") as a continuation-in-part application of the '328 application.

47. Deborah M. Sherman, John C. Clark, John U. Lamer and Stephen A. White were named joint inventors on the '629 application.

48. At least the following Wyeth attorneys were involved in the prosecution of the '328 application: Egon E. Berg, Rebecca R. Barrett, and Steven R. Eck.

49. The '629 application was assigned to Examiner James Spear.

50. The '629 application included the following independent claims:

> 21. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.
>
> 22. A method for eliminating the troughs and peaks of drug concentration in a patients blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

51. Claim 21 of the '629 application was identical to claim 9 of the '137 parent application, prior to its amendment "to avoid rejection over Upton."

52. Claim 22 of the '629 application was substantially similar to claim 10 of the '137 parent application, prior to its amendment "to avoid rejection over Upton."

53. During prosecution, Wyeth added the following new independent claims:

> 23. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated extended release formulation that provides a peak blood plasma level of venlafaxine in from about 5 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.
>
> 24. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated extended release formulation that provides a

peak blood plasma level of venlafaxine in about 6 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

25. A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses o[f] venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about 5 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

26. A method for eliminating the troughs and peaks of drug concentration in a patient s blood plasma attending the therapeutic metabolism f plural daily doses o[f] venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in about 6 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

54. Claims 23-26 of the '629 application were substantially similar to original claims 9 and 10 of the '137 parent application, prior to their amendment "to avoid rejection over Upton."

55. During prosecution of the '629 application, at least Deborah M. Sherman, John C. Clark, John U. Lamer, Stephen A. White, Egon E. Berg, Rebecca R. Barrett, and Steven R. Eck failed to disclose to the new examiner (Examiner James Spear) the earlier examiner's (Examiner Amy Hulina's) requirement for an amendment of the identical and substantially similar claims "to avoid rejection over Upton" and the fact that Wyeth had acquiesced to Examiner Hulia's requirement and agreed to narrow the scope of the identical and substantially similar claims in order "to avoid rejection over Upton."

56. The information withheld by the named inventors and/or prosecuting attorneys was material to the patentability of the pending claims.

57. On information and belief, the named inventors and/or prosecuting attorneys withheld such material information from the examiner in order to prosecute claims substantially similar to the previously rejected claims and did so with an intent to mislead or deceive the USPTO.

58. The '171 patent issued from the '629 application on August 14, 2001.

The '958 Patent

59. On June 19, 2001, Wyeth filed patent application n No. 09/884,412 ("the '412 application") and asserted that it was properly designated as a "divisional" application of the '629 application.

60. Deborah M. Sherman, John C. Clark, John U. Lamer, and Stephen A. White were named joint inventors on the '412 application.

61. At least the following Wyeth attorneys were involved in the prosecution of the '412 application: Rebecca R. Barrett and Egon E. Berg.

62. The '412 application was assigned to Examiner James Spear.

63. The '412 application included the following claims:

> 23. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an extended release formulation that provides a peak blood plasma level of venlafaxine in from about 4 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.
>
> 24. A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, extended release formulation that provides a peak blood plasma level of venlafaxine in from about 4 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

64. Claims 23 and 24 of the '412 application are substantially similar to original claims 9 and 10 of the '137 parent application, prior to their amendment "to avoid rejection over Upton."

65. During prosecution, Wyeth added the following claims to the '412 application:

> 25. A method for providing a therapeutic drug plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an extended release formulation that provides a peak blood plasma level of venlafaxine in from about 5 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

26. A method for providing a therapeutic drug plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an extended release formulation that provides a peak blood plasma level of venlafaxine in about 6 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

27. A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an extended release formulation that provides a peak blood plasma level of venlafaxine in from about 5 to about 8 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

28. A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride which comprises administering orally to a patient in need thereof, an extended release formulation that provides a peak blood plasma level of venlafaxine in about 6 hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

66. Claims 25-28 of the '412 application were substantially similar to original claims 9 and 10 of the '137 parent application, prior to their amendment "to avoid rejection over Upton."

67. During prosecution of the '412 application, at least Deborah M. Sherman, John C. Clark, John U. Lamer, Stephen A. White, Rebecca R. Barrett, and Egon E. Berg failed to disclose to the new examiner (Examiner James Spear) the earlier examiner's (Examiner Amy Hulina's) requirement for an amendment of the identical and substantially similar claims "to avoid rejection over Upton" and the fact that Wyeth had acquiesced to Examiner Hulia's requirement and agreed to narrow the scope of the identical and substantially similar claims in order "to avoid rejection over Upton."

68. The information withheld by the named inventors and/or prosecuting attorneys was material to the patentability of the pending claims.

69. On information and belief, the named inventors and/or prosecuting attorneys withheld such material information from the examiner in order to prosecute claims substantially

similar to the previously rejected claims and did so with an intent to mislead or deceive the USPTO.

70. The '958 patent issued from the '412 application on July 16, 2002.

The '120 Patent

71. On September 12, 2001, Wyeth filed patent application No. 09/950,965 ("the '965 application") as a continuation application of the '412 application.

72. Deborah M. Sherman, John C. Clark, John U. Lamer, and Stephen A. White were named joint inventors on the '965 application.

73. At least the following Wyeth attorneys were involved in the prosecution of the '965 application: Rebecca R. Barrett and Egon E. Berg.

74. The '965 application was assigned to Examiner James Spear.

75. The '965 application included the following claim:

> 23. A method for providing therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an extended release formulation that provides peak blood plasma levels of venlafaxine of no more than about 150 ng/ml, said formulation containing venlafaxine hydrochloride as the active ingredient.

76. Claim 23 of the '965 application was substantially similar to original claims 9 and 10 of the '137 parent application, prior to their amendment "to avoid rejection over Upton."

77. During prosecution of the '965 application, at least Deborah M. Sherman, John C. Clark, John U. Lamer, Stephen A. White, Rebecca R. Barrett, and Egon E. Berg failed to disclose to the new examiner (Examiner James Spear) the earlier examiner's (Examiner Amy Hulina's) requirement for an amendment of the identical and substantially similar claims "to avoid rejection over Upton" and the fact that Wyeth had acquiesced to Examiner Hulia's requirement and agreed to narrow the scope of the identical and substantially similar claims in order "to avoid rejection over Upton."

78. The information withheld by Wyeth's inventors and prosecuting attorneys was material to the patentability of the pending claims.

79. On information and belief, Wyeth's inventors and prosecuting attorneys withheld this material information from the examiner in order to prosecute claims substantially similar to the previously rejected claims and did so with an intent to mislead or deceive the USPTO.

80. The '120 patent issued from the '965 application on June 11, 2002.

First Counterclaim

Declaratory Judgment of Unenforceability of the '171 Patent

81. Orchid Chemicals & Pharmaceuticals Ltd. repeats and realleges the allegations in paragraphs 1-80 of its counterclaims.

82. As described above, the applicants (including Wyeth) violated their duty of candor to USPTO under 35 U.S.C. § 282 and 37 C.F.R. § 1.765 by failing to disclose during prosecution of the '328 application and the '629 application that the previous examiner considered the claimed subject matter unpatentable over Upton and that they had acquiesced and agreed to amendment of the claimed subject matter to avoid rejection over Upton. The applicants' failure to disclose such material information was done with the intent to mislead and deceive. Therefore, the '171 patent is unenforceable.

Second Counterclaim

Declaratory Judgment of Unenforceability of the '958 Patent

83. Orchid Chemicals & Pharmaceuticals Ltd. repeats and realleges the allegations in paragraphs 1-82 of its counterclaims.

84. As described above, the applicants (including Wyeth) violated their duty of candor to USPTO under 35 U.S.C. § 282 and 37 C.F.R. § 1.765 by failing to disclose during prosecution of the '328 application, the '629 application, and the '412 application that the previous examiner considered the claimed subject matter unpatentable over Upton and that they had acquiesced and agreed to amendment of the claimed subject matter to avoid rejection over Upton. The applicants' failure to disclose such material information was done with the intent to mislead and deceive. Therefore, the '958 patent is unenforceable.

Third Counterclaim

Declaratory Judgment of Unenforceability of the '120 Patent

85. Orchid Chemicals & Pharmaceuticals Ltd. repeats and realleges the allegations in paragraphs 1-84 of its counterclaims.

86. As described above, the applicants (including Wyeth) violated their duty of candor to USPTO under 35 U.S.C. § 282 and 37 C.F.R. § 1.765 by failing to disclose during prosecution of the '328 application, the '629 application, the '412 application, and the '120 application that the previous examiner considered the claimed subject matter unpatentable over Upton and that they had acquiesced and agreed to amendment of the claimed subject matter to avoid rejection over Upton. The applicants' failure to disclose such material information was done with the intent to mislead and deceive. Therefore, the '120 patent is unenforceable.

Fourth Counterclaim

Declaratory Judgment of Noninfringement of the '171 Patent

87. Orchid Chemicals & Pharmaceuticals Ltd. repeats and realleges the allegations in paragraphs 1-86 of its counterclaims.

88. Orchid Chemicals & Pharmaceuticals Ltd. has not infringed any claim of the '171 patent by filing ANDA No. 91-123, and the commercial manufacture, use, importation, offer for sale and/or sale of the product described in ANDA No. 91-123 will not infringe any valid and enforceable claim of the '171 patent.

Fifth Counterclaim

Declaratory Judgment of Noninfringement of the '120 Patent

89. Orchid Chemicals & Pharmaceuticals Ltd. repeats and realleges the allegations in paragraphs 1-88 of its counterclaims.

90. Orchid Chemicals & Pharmaceuticals Ltd. has not infringed any claim of the '120 patent by filing ANDA No. 91-123, and the commercial manufacture, use, importation, offer for sale and/or sale of the product described in ANDA No. 91-123 will not infringe any valid and enforceable claim of the '120 patent.

Sixth Counterclaim

Declaratory Judgment of Noninfringement of the '958 Patent

91. Orchid Chemicals & Pharmaceuticals Ltd. repeats and realleges the allegations in paragraphs 1-90 of its counterclaims.

92. Orchid Chemicals & Pharmaceuticals Ltd. has not infringed any claim of the '958 patent by filing ANDA No. 91-123, and the commercial manufacture, use, importation, offer for sale and/or sale of the product described in ANDA No. 91-123 will not infringe any valid and enforceable claim of the '958 patent.

Seventh Counterclaim

Declaratory Judgment of Invalidity of the '171 Patent

93. Orchid Chemicals & Pharmaceuticals Ltd. repeats and realleges the allegations in paragraphs 1- 92 of its counterclaims.

94. Each claim of the '171 patent is invalid for failure to comply with one or more provisions of Title 35, United States Code, including, inter alia, §§ 101, 102, 103, 112, and/or for double patenting.

Eighth Counterclaim

Declaratory Judgment of Invalidity of the '120 Patent

95. Orchid Chemicals & Pharmaceuticals Ltd. repeats and realleges the allegations in paragraphs 1-94 of its counterclaims.

96. Each claim of the '120 patent is invalid for failure to comply with one or more provisions of Title 35, United States Code, including, *inter alia*, §§ 101, 102, 103, 112, and/or for double patenting.

Ninth Counterclaim

Declaratory Judgment of Invalidity of the '958 Patent

97. Orchid Chemicals & Pharmaceuticals Ltd. repeats and realleges the allegations in paragraphs 1-96 of its counterclaims.

98. Each claim of the '958 patent is invalid for failure to comply with one or more provisions of Title 35, United States Code, including, inter alia, §§ 101, 102, 103, 112, and/or for double patenting.

Prayer for Relief

WHEREFORE, Orchid Chemicals & Pharmaceuticals Ltd. respectfully requests this Court enter a Judgment and Order:

A. dismissing the Complaint, and each and every Claim for Relief contained therein, with prejudice;

B. declaring the claims of United States Patent No. 6,274,171 unenforceable due to inequitable conduct;

C. declaring the claims of United States Patent No. 6,403,120 unenforceable due to inequitable conduct;

D. declaring the claims of United States Patent No. 6,419,958 unenforceable due to inequitable conduct;

E. declaring that no valid and enforceable claim of United States Patent No. 6,274,171 has been or would be infringed by Orchid Chemicals & Pharmaceuticals Ltd. directly, by inducement of infringement, or otherwise;

F. declaring that no valid and enforceable claim of United States Patent No. 6,419,958 has been or would be infringed by Orchid Chemicals & Pharmaceuticals Ltd. directly, by inducement of infringement, or otherwise;

G. declaring that no valid and enforceable claim of United States Patent No. 6,403,120 has been or would be infringed by Orchid Chemicals & Pharmaceuticals Ltd. directly, by inducement of infringement, or otherwise;

H. declaring the claims of United States Patent No. 6,274,171 invalid;

I. declaring the claims of United States Patent No. 6,403,120 invalid;

J. declaring the claims of United States Patent No. 6,419,958 invalid;

K. declaring this case exceptional pursuant to 35 U.S.C. § 285 and awarding Orchid Chemicals & Pharmaceuticals Ltd. its attorneys' fees, costs and expenses; and

L. granting such other and further relief as this Court may deem just and proper.

Dated: September 2, 2009

s/ Jason B. Lattimore

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Attorneys for defendants Orchid Chemicals & Pharmaceuticals, Ltd. and Orgenus Pharma, Inc.

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I hereby certify that to the best of my knowledge the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

s/ Jason B. Lattimore
Jason B. Lattimore

Dated: September 2, 2009